REMARKS

Rejection of Claims and Traversal Thereof

In the October 22, 2003 Office Action,

claims 47-75 were rejected under 35 U.S.C. §101 as claiming the same invention as that of claims 20-35 of prior U.S. Patent No. 5,807,858 issued to Chang, et al. (hereinafter Chang '858).

This rejection is traversed and reconsideration of the patentability of the pending claims is requested in light of the following remarks.

Rejection under 35 U.S.C. § 101

According to the Office:

> "The present application teaches a composition comprising a pharmaceutical composition comprising a bioactive compound mediating respiratory depression, muscle rigidity, and/or nausea/vomiting as an unwanted side effects (an opiate compound) and a non-polypeptide δ receptor activating agent (3290W93, a diarylmethylpiperazine); and the patent application teaches a pharmaceutical composition comprising a therapeutic agent having respiratory depression and an effective amount of a compound of formula I which is the same compounds of the present application's pharmaceutical composition second component.
>
> The present application teaches the bioactive compounds are opiate compounds and the patented application teaches the therapeutic agent is an opiate compound too (see claims 33 and 34 of the present application)."

Thus, the Office contends that the claims of present application recite the same invention as Chang '858. Applicants vigorously disagree.

Under 35 U.S.C. §101, a person is entitled to a patent, unless the Office can establish a *prima facie* case of double patenting. The Office must show that the claims in the present application are **identical** to the subject matter recited in Chang '858. Thus, the Office must show that the **same invention is being claimed twice.**

It is well settled in the law that a double patenting determination involves two inquiries. (*See In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993)). First, is the same invention claimed

twice? *General Foods Corp. v. Studiengesellschaft Kohle mbH*, 23 USPQ2d 1839, 1843 (Fed. Cir. 1992). This inquiry hinges upon the scope of the claims in question. *In re Vogel*, 164 USPQ 619 (CCPA 1970). The Court in *In re Vogel*, held that:

> "By the same invention we mean identical subject matter. Thus the invention defined by a claim reciting 'halogen' is not the same as that defined by the claim reciting 'chlorine,' because the former is broader than the latter."

Thus, if the claimed inventions are not **identical in scope** a rejection under U.S.C. §101 is not proper.

With regards to the first inquiry, claim 47 of the present application recites a composition comprising the following elements (limitatitons):

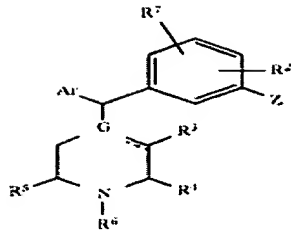
> 1. an effective amount of a bioactive compound mediating respiratory depression, muscle rigidity, and/or nausea/vomiting; and
>
> 2.a non-polypeptide δ receptor activating agent effective for combating said side effect.

The compositions of claim 47 include a broad genus of non-polypeptide δ receptor activating agents that can combat the negative side effects of the bioactive compound.

A comparison of claim 47 (present application) and claim 20 of Chang '858 reveals that claim 20 recites a species of the broad claim 47. Specifically, claim 20 defines use of a composition comprising diarylmethylpiperazine compounds as the non-polypeptide δ receptor agent, which is a species of the genus recited in claim 47 of applicants' present application. **Thus, the claims are not identical in scope.** As stated above, if one claimed invention has a broader scope than the other, a rejection under U.S.C. §101 is not proper.

Moreover, double patenting must be determined by an analysis of the claims as a whole. *Carman Indus., Inc. v. Wahl*, 220 USPQ 481 (Fed. Cir. 1983). Claim 20 of Chang '858, which is relied on by the Office to show double patenting, defines **three (3)** elements, including:

> **1. an effective amount of a therapeutic agent having a respiratory depression side effect;**
>
> **2. an effective amount of a compound for reducing, treating or preventing depression of the formula**



(I)

wherein:

Ar is a 5- or 6-member carbocyclic aromatic ring and having on a first carbon atom thereof a substituent Y and on a second ring carbon thereof a substituent R^1,

Y is selected from the group consisting of:

hydrogen;

halogen;

C_1–C_6 alkyl, C_2–C_6 alkenyl, C_2–C_6 alkynyl;

C_1–C_6 haloalkyl;

C_1–C_6 alkoxy;

C_3–C_6 cycloalkoxy;

sulfides of the formula SR^8 where R^8 is C_1–C_6 alkyl, C_2–C_6 alkenyl, C_2–C_6 alkynyl, C_3–C_6 cycloalkyl, arylalkyl having a C_5–C_{10} aryl moiety and an C_1–C_6 alkyl moiety, or C_5–C_{10} aryl;

sulfoxides of the formula SOR^8 where R^8 is the same as above;

sulfones of the formula SO_2R^8 where R^8 is the same as above;

nitrile;

C_1–C_6 acyl;

alkoxycarbonylamino (carbamoyl) of the formula $NHCO_2R^8$ where R^8 is the same as above;

carboxylic acid, or an ester, amide, or salt thereof;

aminomethyl of the formula $CH_2NR^9R^{10}$ where R^9 and R^{10} may be the same or different, and may be hydrogen, C_1–C_6 alkyl, C_2–C_6 alkenyl, C_2–C_6 alkynyl, C_2–C_6 hydroxyalkyl, C_2–C_6 methoxyalkyl, C_3–C_6 cycloalkyl, or C_5–C_{10} aryl, or R^9 and R^{10} together may form a ring of 5 or 6 atoms, the ring atoms selected from the group consisting of N and C;

carboxamides of the formula $CONR^9R^{10}$ where R^9 and R^{10} are the same as above, or C_2–C_{30} peptide conjugates thereof; and

sulfonamides of the formula $SO_2NR^9R^{10}$ where R^9 and R^{10} are the same as above;

Z is selected from the group consisting of:

hydroxyl, and esters thereof;

hydroxymethyl, and esters thereof; and

amino, and carboxamides and sulfonamides thereof;

G is nitrogen;

R^1 is hydrogen, halogen, or C_1–C_4 alkyl, C_2–C_4 alkenyl, C_1–C_4 alkynyl;

R^2 is hydrogen, halogen, or C_1–C_4 alkyl, C_2–C_4 alkenyl, C_1–C_4 alkynyl;

R^3, R^4 and R^5 may be the same or different, and are independently selected from hydrogen and methyl, and wherein at least one of R^3, R^4 or R^5 is not hydrogen, subject to the proviso that the total number of methyl groups does not exceed two, or any two of R^3, R^4 and R^5 together may form a bridge of 1 to 3 carbon atoms;

R^6 is selected from the group consisting of:

hydrogen;

C_1–C_6 alkyl, C_2–C_6 alkenyl, C_2–C_6 alkynyl;

C_3–C_6 cycloalkyl;

arylalkyl having C_5–C_{10} aryl and C_1–C_6 alkyl moieties;

alkoxyalkyl having C_1–C_4 alkoxy and C_1–C_4 alkyl moieties;

C_2–C_4 cyanoalkyl;

C_2–C_4 hydroxyalkyl;

aminocarbonylalkyl having a C_1–C_4 alkyl moiety; and

$R^{12}COR^{13}$, where R^{12} is C_1–C_4 alkylene, and R^{13} is C_1–C_4 alkyl or C_1–C_4 alkoxy; and

R^7 is hydrogen or fluorine,

or a pharmaceutically acceptable ester or salt thereof.

and

3. said compound acting to attenuate the respiratory depression side effect of the therapeutic agent without precluding the therapeutic efficacy of the therapeutic agent.

Clearly, the compositions of Chang '858 define a third necessary element, wherein compound (2) must reduce the negative side effects of agent (1) without affecting the therapeutic efficacy of agent (1).

In contrast, the claims of the present invention do not include the third element as recited in Chang '858, and as such, is not patented in Chang '858. It is evident that the claims of the present application and those of Chang '858 are not co-extensive in scope. If one claimed invention has a broader scope than the other, then the same invention is not claimed twice and the second inquiry[1] must be made as to whether the claims of the application define an obvious variation of the other patent claim which may be overcome by filing a terminal disclaimer.

Applicants submit that the Office has failed to establish a *prima facie* case of same-invention double patenting and request that the rejection under 35 U.S.C. §101 be withdrawn.

Conclusion

Applicants have satisfied all the requirements for patentability. All pending claims are free of the art and fully comply with the requirements of 35 U.S.C. §112. It therefore is requested that Examiner Weddington reconsider the patentability of claims 47-75 in light of the distinguishing remarks herein and withdraw all rejections, thereby placing the application in condition for allowance. Notice of the same is earnestly solicited. In the event that any issues remain, Examiner Weddington is requested to contact the undersigned attorney at (919) 419-9350 to resolve same.

[1] *Id. In re Goodman*

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Respectfully submitted,

Marianne Fuierer
Registration No. 39,983
Attorney for Applicants

INTELLECTUAL PROPERTY/
TECHNOLOGY LAW
P.O. Box 14329
Research Triangle Park, NC 27709
Phone: (919) 419-9350
Fax: (919) 419-9354
Attorney File: 4080-109 CIP DIV 2

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